AUG 3 2000

K001553

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:

Vital Signs, Inc.
20 Campus Road
Totowa, NJ 07512-1200

Contact Person:

Anthony P. Martino
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Summary Date: May 17, 2000

Name of Device: Breas PV 100 CPAP System

Common Name: CPAP System

Classification Name: Non-continuous ventilator (21 CFR 868.5905)

Product Code: 73 BZD

Predicate Device(s): Respironics Solo® CPAP System (K961626)

ResMed Sullivan® III Nasal CPAP System (K930656)

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vital signs inc.

Device Description:

The Breas PV 100 CPAP System is a microprocessor-controlled device providing continuous positive airway pressure in the range of 4 to 16 cm H_2O. The primary component is a blower that generates airflow. The blower assembly consists of a DC servo-motor that drives a fan, entraining ambient air through a filter and pressurizing it to provide the prescribed airflow with CPAP for the patient. The microprocessor controls the motor and hence the speed of the fan. The device incorporates a pressure sensor that monitors the output pressure and provides feedback to the microprocessor. The airflow is delivered via a single lumen outlet tube that may be connected to various non-invasive patient interfaces, such as nasal masks. The device can be used with an external DC power source when AC mains line voltage is not available. This DC power source capability is not intended as a battery power back-up system for any critical treatment applications. An optional accessory Remote Control Module may be connected that enables clinicians to operate the device without using the control and setting panels on the PV 100 device itself. The device and accessories are not sterile. The outer dimensions of the PV 100 device housing are 7.1 x 3.9 x 10.8 inches, and it weighs 5.3 pounds.

Intended Use:

The Breas PV 100 CPAP System is intended to deliver Continuous Positive Airway Pressure (CPAP) therapy for the treatment of adult Obstructive Sleep Apnea (OSA).

Comparison of Use and Technological Characteristics:

The Breas PV 100 CPAP System may be used in clinical settings (e.g., hospitals, sleep laboratories, sub-acute care institutions) and home environments and must be prescribed by a physician. It is not intended for life support or life sustaining applications or for transport of critical care patients.

As compared with the cited predicate devices, the Breas PV 100 CPAP System has:

Same intended uses

Same environments of use

Similar design

Same technology (microprocessor-controlled blower as air source)

Same materials (with particular reference to the air flow pathway)

The differences that do exist are minimal and involve primarily user preference features. The Breas PV 100 CPAP System has additional display indicator and

audible alarm features as well as lockout features (to provide clinicians with optional means to control the ability of patients to change pressure settings). These features are described in labeling for the device that includes an Operator Manual.

Summary of Performance Testing:

1) Non-clinical testing was conducted to verify that the Breas PV 100 CPAP System is capable of meeting its stated performance specifications and that all Risk Analysis issues have been appropriately addressed. The device passed all tests.

2) Testing was conducted to demonstrate compliance with applicable requirements in the November 1993 draft "Reviewer Guidance for Premarket Notification Submissions" published by the FDA's Division of Cardiovascular, Respiratory, and Neurological Devices. The testing included but was not limited to:

   - Electrical Safety testing per IEC 601
   - Electromagnetic Compatibility testing (EMC testing)
   - Mechanical Safety testing
   - Environmental testing
   - Functional testing

   The device passed all tests.

3) All device software was documented and tested in accordance with the FDA's May 29, 1998 "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices". The device passed all tests.

4) Clinical studies were not required to support a substantial equivalence determination.

Conclusions:

The Breas PV 100 CPAP System meets its stated performance specifications and criteria outlined in the Reviewer Guidance publications referenced above. We conclude that the device is capable of operating safely in its intended environments and will be effective in fulfilling its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 2000

Mr. Anthony P. Martino
Vital Signs, Inc.
20 Campus Road
Totowa, NJ 07512

Re: K001553
Breas PV 100 CPAP System
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: July 20, 2000
Received: July 21, 2000

Dear Mr. Martino:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001553

Device Name: Breas PV 100 CPAP System

Indications for Use: The Breas PV 100 CPAP System is intended to deliver Continuous Positive Airway Pressure (CPAP) therapy for the treatment of adult Obstructive Sleep Apnea (OSA).

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Division of Cardiovascular & Respiratory Devices
510(k) Number K001553

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)